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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,652	03/13/2001	D. Laksen Sirimanne	END-5247USCNT1	4202

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EXAMINER	
SMITH, RUTH S	

ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
05/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/805,652	SIRIMANNE ET AL.	
	Examiner	Art Unit	
	Ruth S. Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,16,17,22-24,31,33,34 and 111-121* is/are pending in the application.

4a) Of the above claim(s) *112-121* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,16,17,22-24,31,33,34 and 111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on April 10, 2009 has been entered.

Election/Restrictions

Newly submitted claims 112-121 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly submitted claims are directed to the combination of a needle and marker materials which can be used as a fiducial marker in an imaging procedure and doesn't require the specific marking materials set forth in the subcombination. The previously presented claims are directed to the subcombination of a cavity marker.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 112-121 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claims 1-7,16,17,22-24,31,33,34,111 are objected to because of the following informalities: In claim 1,it is unclear as to whether the term "made from" is inclusive or exclusive. In claim 111, it is unclear as to what further structural limitation has been set forth. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7,16,17,22-24,31,33,34,111 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification, as originally filed, fails to disclose a cavity marking device having at least two bodies made from different materials which are ultrasonically detectable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7,16,17,22-24,31,33,34,111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 sets forth that the implantable bodies are ultrasonically detectable, however, the claim fails to set forth any structural limitation that would provide that function such as an echogenic coating. It is unclear as to how the materials set forth in claims 3-7 allow for the bodies to be ultrasonically detectable. In claim 22, it is unclear as to whether the suture is in addition to the cross pattern

set forth in claim 1. In claim 23, it is unclear as to whether the wire is in addition to the cross pattern set forth in claim 1. In claim 24, it is unclear as to whether the distinguishing pattern is in addition to the cross pattern set forth in claim 1. In claims 31,33, "the at least two implantable bioabsorbable bodies" lacks antecedent basis. Claim 111 includes functional language unsupported by structure to produce such a function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7,16,22,23,24,31,33,34,111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al (2002/0012652) in view of Violante et al (6,106,473) and Crittenden (6,197,324) and Suding et al (5,632,775) or Michelson (4,985,019). Levy et al disclose a bioactive agent in a microsphere. The agent can include substances to facilitate visualization. The microspheres can be used in combination with a matrix. The matrix can be biodegradable. The matrix may take the form of a sponge or an implant, or gel. The microspheres are then disposed within the matrix. Levy et al fails to disclose the use of materials that are ultrasonically detectable. Violante et al disclose the use

of echogenic coatings that can be applied to pellets or implants to allow them to be visualized using ultrasound imaging. The coatings can be applied to capsules. It would have been obvious to one skilled in the art to have modified Levy et al such that the matrix and microspheres are coated with an echogenic material in order for them to be properly located using ultrasound. Such a modification ensure that the matrix/microspheres are properly positioned in the patient. Levy et al also fails to disclose the use of a radiopaque marker and a cross pattern on the outside of the device. Crittenden disclose the use of a radiopaque marker in a pellet in order to show that its location can be properly determined. Suding et al and Michelson disclose the use of radiopaque patterns so that an element can be properly located using x-ray imaging. It would have been obvious to one skilled in the art to have further modified Levy et al such that the first and/or second bodies includes a radiopaque material where the material is arranged in a pre-defined pattern to ensure that the matrix/microsphere can be properly located using x-ray. Such a modification would allow the device to be used with a plurality of well known types of imaging modalities that each can be used to ensure it proper placement in the patient. With respect to claims 3,6, the materials set forth are well known radiopaque materials and the selection of one would have been obvious based upon suitability for intended use. With respect to claim 16, it is a well known expedient in the art to provide a pain killing substance in combination with a medical procedure so as to reduce the pain that the implantation can cause. With respect to claims 22-24,31 the specific element used to create the pattern and the shape of the implant would have been an obvious design choice in the absence of any showing of criticality or unexpected result. With respect to claims 33,34,111 the use of a sponge would include pores that allow tissue growth and an expandable body. It should be noted that the intended use of the device as set forth in the claims is not given patentable weight. The modified device of Levy et al is capable of functioning as set forth.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al (2002/0012652) in view of Violante et al (6,106,473) and Crittenden (6,197,324) and Suding et al (5,632,775) or Michelson (4,985,019) as applied to claim 1 above, and further in view of Good (6,666,811). Good discloses an implantable body including a hemostatic material enabling it to be easily implanted in the tissue. It would have been obvious to one skilled in the art to have further modified Levy et al such that it includes a hemostatic material which enhances its ability to be implanted in the body.

Response to Arguments

Applicant's arguments with respect to claims 1-7,16,17,22-24,31,33,34,111 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

RSS